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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,567	09/05/2006	Joern Borgert	DE040071US1	7279

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER	
GUPTA, VANI	

ART UNIT	PAPER NUMBER
3777	

MAIL DATE	DELIVERY MODE
01/04/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,567	BORGERT ET AL.	
	Examiner	Art Unit	
	VANI GUPTA	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 24, 2010 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 6 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 6, the claimed memory ("storage device") includes a road map and the monitoring unit records the position "using" the road map. However, it not clear how one would record a position with a map. One of ordinary skill in the art may be able to either perform recording a position on a map or determining a position using a map, but not what is in the claim. Applicant is required to amend the claim to clarify this issue; preferably something along the lines of what is included in paragraph 12 of the present specification.

Regarding Claim 13, it is claimed that the aneurysm is imaged using "preferably" x-ray or use of contrast agent. The resulting claim scope is unclear and, therefore, the claim is rendered indefinite. It is not clear whether the preferred detail is required or not.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 5, 6, 8, 10, 11, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al. (US 6,146,373) in view of Eick et al. (US 6,955,674 B2).

Regarding Claim 1, Cragg et al. (hereinafter Cragg) discloses a catheter apparatus for therapy, such as therapeutic occlusion of an area of a heart, the catheter apparatus comprising:

a. a catheter **(figs. 1 and 2, (10))** configured to inject a filling or plugging material an aneurysm (col. 4, line 25 – col. 5, line 7);

b. an active locator attached to the catheter **(fig. 6, (50) and (52))** and configured to provide coordinates to determine spatial position and orientation of the catheter (col. 9, ll. 40 – 50); and

c. a pump configured to controllably supply filling material to the catheter (col. 6, ll. 24 – 31).

However, Cragg differs from Claim 1 in that Cragg does not disclose specifically a monitor connected to the active locator and the pump, wherein the monitor is configured to monitor the spatial position and/or orientation of the catheter to detect emergence of the catheter from the aneurysm during the injection of the drug into the aneurysm, and configured to stop the supply of the drug in response to the detected emergence.

Nonetheless, Eick et al. (hereinafter Eick) suggests a system for tracking the position of the catheter relative to the treatment sight by monitoring the x-axis of the coordinate system that the catheter is tracked within. When there is a change in position along the X-axis such that the change in position is higher than an allowed limit, the catheter is considered "dislocated" (col. 3, line 65 – col. 4, line 27), and "terminates" treatment upon dislocation (col. 6, ll. 25 – 27).

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Cragg and Eick before one at the time the invention was made, to modify the embolization-treatment-of-aneurysms device and method teachings of Cragg with the catheter-dislocation-monitoring-and treatment-termination-method teachings of Eick so that one could ensure that only the targeted region is treated and surrounding healthy tissue is not damaged (Eick: col. 1, ll. 55 – 58).

Regarding claims 5 and 8, Cragg in view of Eick suggests a catheter, a pump device and an electromagnetic locating device, and monitoring capabilities for monitoring the spatial position and/or orientation of the catheter based on the provided coordinates from the locator for detecting emergence of the catheter from the region of interest during injection of the filling material into the aneurysm, and thereupon stopping the supply of the drug (please see rejections of Claim 1).

Regarding Claim 6, in light of the 112 second paragraph rejection above and for purposes of examination, Examiner interprets claim 6 to mean that a road map is generated based on the anatomy of the region of interest and includes position of the aneurysm, and further helps determine that the catheter is in a correct position to provide treatment. Eick suggests a control circuitry ("LocaLisa system" and "microprocessor") containing storage space for storing

("collecting") a "road map" and is designed to record measured position and/orientation data ("x-y-z coordinates) from the locator (see rejection of Claim 1) using the road map (col. 6, ll. 25 – 63). Applicant should note that control circuitry *(or "LocaLisa" system* - col. 1, ll. 15 – 20) comprises a computer, which would inherently comprise a storage device capable of storing any type of information, including a road map.

Regarding Claim 10, Cragg teaches that the plugging material can comprise a curable polymer material, plastic beads, a plastic coil, a hydrogel and/or a fibrin sponge, as is known in the art (col. 1, ll. 25 – 33).

Regarding Claim 11, please refer to rejections of claims 1 and 5.

Regarding Claim 12, Eick teaches that the position of the locator is recorded using a road map of locator positions, the detecting of the emergence of the catheter from the aneurysm further being based on the road map (see rejection of Claim 6).

Regarding Claim 14, Cragg in view of Eick teaches that the navigation of the catheter in the vascular system is assisted by determining the position of the active locator, as discussed in the rejection of Claim 11.

2. Claims 2, 7, 9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg is view of Eick as applied to claims 1 and 5 above and further in view of Kucharczyk et al. (US 6,463, 317 B1).

Regarding claim 2, Cragg in view of Eick teaches each and every limitation of the claim, as discussed above in reference to claim 1.

However, Cragg in view of Eick does not teach the catheter apparatus, wherein the active locator comprises a magnetic field sensor.

Nonetheless, Kucharczyk et al. (hereinafter Kucharczyk) teaches an aneurysm treatment device that comprises a magnetic field sensor for tracking the position of the catheter. Moreover, Kucharczyk suggests that it is known in the art to use magnetic-field based sensors for tracking positions of catheters (col. 4, ll. 43 – 67).

Accordingly, it would have been obvious to one of ordinary skill in the art, having the teachings of Cragg and Eick, and Kucharczyk before one at the time the invention was made, to modify the aneurysm device and method teachings of Cragg and Eick with the magnetic-field based sensors for tracking positions of aneurysm-treatment-catheter teachings of Kucharczyk so that one could visualize the catheter during treatment using magnetic resonance imaging, if so required (Kucharczyk: col. 10, ll. 21 – 24).

Regarding Claim 7, Kucharczyk suggests that the apparatus of Claim 5 further comprises an X-ray imaging device (col. 9, ll. 37 – 38).

Regarding Claim 9, Applicant should note that it would be inherent matter of design choice that if Cragg in view of Eick further in view of Kucharczyk discusses a locating device that works in conjunction with a magnetic field sensor device (rejection of Claim 2), then the locating device would comprise capabilities for generating an electromagnetic field for the magnetic field sensor to sense. The generation of an electromagnetic field that is spatially and/or temporally inhomogeneous is commonplace, as is known in the art.

Regarding Claim 13, Kucharczyk suggests that the catheter and the region of interest - such as an aneurysm – are imaged together at the start of embolization, preferably by means of X-rays or with administration of a contrast agent (col. 10, line 18; col. 13, ll. 25 – 30).

Response to Arguments

3. Applicant's arguments with respect to claims 1, 2, and 5 – 14 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Thursday (8:30 am - 6:00 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached on 571-272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3777

/Eric F Winakur/
Primary Examiner, Art Unit 3777